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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,671	04/24/2000	Michael Stephen Austin	792-21 RCE	7622

23869 7590 04/15/2009  
HOFFMANN & BARON, LLP  
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EXAMINER
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COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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04/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/556,671	<b>Applicant(s)</b> AUSTIN, MICHAEL STEPHEN	
	<b>Examiner</b> DAVID COMSTOCK	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-15, 17-24, 27-31, 33-37 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-15, 17-24, 27-31, 33-37 and 42-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

In view of the arguments in the appeal brief filed on 15 January 2009, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing this action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 9, 11-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Cragg (5,405,377).

Cragg discloses the claimed endoluminal prosthesis including a hollow tubular body, e.g., 13, and a stent scaffold, the stent scaffold having V-shaped or quadrilateral-shaped cells, and consisting essentially of helically wound undulating wires having alternating peaks and valleys to define turns thereat (see, e.g., Figs. 1, 2 and 7-10 and col. 2, lines 40-49). The hollow tubular body comprises at least one segment of curvature (e.g. the shape of its circular cross-section or profile). The segment of curvature comprises an inside of the curvature and an outside of the curvature (e.g., inside and outside the tube). The turns are distributed substantially equally and uniformly along the length of the prosthesis, including being distributed substantially equally and uniformly along the length of the segment of curvature, to provide a constant pitch of the wires. The segment of curvature is curved in a plane with respect to the central axis of the body (e.g., in a plane normal to the central axis of the body). The prosthesis approximates the shape of a vascular lumen where it will be placed. The device can be formed of various materials such as polymers and/or elastic shape memory materials such as nitinol (see, e.g., col. 2, lines 50-59). Peaks of adjacent undulating wires are interconnected (see, e.g., Figs, 1, 2 and 9). The hollow tubular body comprises a thin-walled tube material that can be on the outside or inside of the stent scaffold (see, e.g., Figs. 7-9 and col. 3, lines 13-32). The device is formed around a mandrel (see, e.g., col. 3, lines 33-50).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-7, 18-24, 27-31, 33-37 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg (5,405,377) in view of Pinchuk (5,855,598).

Cragg discloses the claimed invention except for the curved, tapered, and/or branched shape (including openings thereat). Pinchuk also discloses an endoluminal prosthesis and teaches that the prosthesis may be curved, tapered, and/or branched, in order to provide a form suitable for the location at which it will be used (e.g., a branched arterial lumen) (see, e.g., Figs. 15 and 17 and col., 3, lines 1-2 and 40-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided endoluminal prosthesis of Cragg with curves, tapers, and/or branches, etc., in view of Pinchuk, in order to provide a form suitable for locations at which the prosthesis may be needed. Determining the number of curves or the location thereof, would have been obvious, e.g., to provide a form suitable for a location where the device is needed, since it has been held that determining the location for features of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. In addition, the mere duplication of the features of an invention (here, the curves of the prosthesis, to provide a form suitable for a location where the device is needed) would involve only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. At a

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point along the body, for example, at the branch junction, the cross-section is non-circular (e.g., it is oval or figure-eight shaped). The curvature would cause the pitch of the wires to have an increased pitch along an outside segment and a reduced pitch along an inside segment. The intended use of winding the prosthesis around a mandrel to achieve the desired pitch has not been given weight, since it appears that this amounts to a statement of intended use for which the device of the combination of Cragg and Pinchuk would be capable. In addition, it appears to be a product-by-process limitation, wherein, since the resulting product is not different, the way in which it is formed is not relevant to claims directed to the apparatus (as opposed to a method). In any event, determining the appropriate pitch for the wires, e.g., to provide a form suitable for locations at which the prosthesis may be needed, would be obvious, since it has been held that where the general conditions of a claim are disclosed in the prior art (i.e., a prosthesis having a wire pitch and being modified to curve so as to provide a form suitable for a location where it is needed), discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's

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supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/  
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733